UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,102	11/13/2001	Robert B. Fox	101881-0002	1824

21125 7590 10/07/2003

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER	
MAKI, STEVEN D	

ART UNIT	PAPER NUMBER
1733	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/053,102	Applicant(s) FOX ET AL.
	Examiner Steven D. Maki	Art Unit 1733

-- The MAILING DATE of this communication app ars on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1) The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "62" and "66" have both been used to designate the end of sheet 10. It is suggested to change "62" in figure 8 to --66--. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2) The disclosure is objected to because of the following informalities:

- page 6 line 18 uses "@" (should "@" be a --©--?);
- page 7 line 18 uses "@" (should "@" be a --©--?);
- on page 8 line 13, "ends 62, 64" should be --ends 64, 66--
- page 9 line 7 describes "machine=s";
- page 10 line 8 describes "□" instead of --degrees--;
- on page 10 line 19, "90 100" should be --90--;
- the specification does not describe "18" and "48" indicated in figure 5.

Appropriate correction is required.

3) Claim 3 is objected to because of the following informalities: Claim 3 describes "□" instead of --degrees--. Appropriate correction is required.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 describes "automated process". One of ordinary skill in the art is not reasonably appraised of the scope of protection afforded by this language. It is unclear which step(s), if any, cause the claimed process to be "automated" instead of for example a process of manufacture by hand.

In claim 10, the use of etc. in the Markush group makes the scope of this claim unclear.

6) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7) **Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Footscreening ("Foot Screening-Care of the Foot in Diabetes" / supplied by applicant) in view of McGill et al ("Use of the Semmes-Weinsten 5.07/10 Gram Monofilament: the Long and the Short of it" / supplied by applicant) and further in view of Weihrauch (US 4807938) and/or Adhesives Technology Handbook.**

Foot Screening includes "Making LEAP Filaments: Instructions for Camera Art Work". "Making LEAP Filaments", directed to Lower Extremity Amputation Protection, discloses making a medical test implement (a LEAP testing implement) by:

providing a sheet such as index card stock,

providing a 5.07/10gm nylon filament;

printing on the sheet;

cutting the sheet to a size of 2 inches by 1 ¾ inches (50.8 mm to 44.5 mm);

perforating the sheet along a line so as to defines two halves;

applying adhesive to the sheet;

folding the sheet along the perforated line such that the filament is adhered between the two portions of the sheet and extends a distance of 37-39 mm from an edge of the folded sheet. The step of detaching the first material reads on cutting the sheet to size. The step of mechanically mating reads on the adhering step. "Making LEAP Filaments" does not recite detaching / heating the second material.

As to claim 1, it would have been obvious to one of ordinary skill in the art to cut a nylon monofilament to the length for allowing it to protrude out of the folded sheet by 37-39 mm as described by "Making LEAP Filaments" since McGill et al, also directed to Lower Extremity Amputation Protection, teaches cutting a nylon filament to obtain a desired length for Lower Extremity Amputation Protection. The claimed step of detaching of the second material reads on a step of cutting a monofilament as suggested by McGill et al.

As to "heating the second material", it would have been obvious to one of ordinary skill in the art to heat a continuous nylon filament before since (1) McGill et al, also directed to Lower Extremity Amputation Protection, emphasizes that (a) non-uniformity in filaments causes difficulties in applying a correct buckling force and (b) reliability of these filaments is essential and (2) it is known in the filament art to improve the uniformity of a filament by heating the filament to eliminate curvature and make the filament straight as evidenced for example by Weihrauch. The need for the filament to be straight is additionally suggested by the following statement in "Foot Screening-Care

of the Foot in Diabetes" : "Occasionally you will find a filament that seems to be abnormal (it may be thinner or it may be bent). Just discard that filament. A small bend in the filament will not distort the delivery of 10 grams of force. However, one that is really bent may. We suggest that you throw questionable filaments away".

Alternatively: it would have been obvious to one of ordinary skill in the art to use a heat activated adhesive and apply heat to the filament and the cut sheet to cause bonding since (1) "Making LEAP filaments" suggests adhering the filament between the portions of the folded cut sheet using adhesive (adhesive tape) and (2) Adhesives Handbook teaches that known adhesive include heat activatable adhesive (for example heat activatable adhesive on tapes) wherein the assembly of parts to be bonded are heated and occasionally the parts are heated before the parts are mated.

In claim 1, "automated process" fails to require methodology not suggested by the above applied prior art.

As to claims 2-4, the claimed temperature and time would have been obvious and could have been determined without undue experimentation in view of Weihrauch's suggestion to heat a filament to straighten the filament.

As to claims 5-8, the claimed dimensions of the second material (corresponding to the filament) and the first material (corresponding to the sheet) would have been obvious in view of (a) "Making LEAP Filaments" teaching to use the sheet and filament to make a device for Lower Extremity Amputation Protection and (b) the specific dimensions disclosed by "Making LEAP Filaments" for the cut sheet and the filament.

As to claims 9-10, note "Making LEAP Filaments" suggestion to use a sheet such as an index card (paperboard). As to claim 10, a plastic sheet is taken as well known / conventional per se); it being noted that the suggestion to use a sheet comes from "Making LEAP Filaments".

As to claims 11-13, note the nylon filament suggested by "Making LEAP Filaments".

As to claim 14, the limitation therein would have been obvious in view of Footscreening's suggestion to inspect for bent filaments and the testing of filaments suggested by McGill et al.

As to claims 15-16, note the teaching in "Making LEAP Filaments" to perforate (score) and fold the sheet and to dispose the filament between the folded portions of the sheet. As to claim 16, it would have been obvious to use a tweezers to locate the filament between the folded portions of the sheet since (1) the nylon filament has a short and (2) it is taken as well known / conventional in general to handle small objects using tweezers.

As to clams 17-18, note the suggestion from Adhesives Handbook to use heat activatable coatings to bond parts together.

8) **Claims 1 and 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaacs et al (US 6113551) in view of McGill et al ("Use of the Semmes-Weinsten 5.07/10 Gram Monofilament: the Long and the Short of it" / supplied by applicant), Schwobel et al (US 6207000), Mohr (US 3616083) and Orzelek et al (US 4021289).**

Isaacs et al, directed to a medical test implement for the care and treatment of diabetes, teaches bonding a nylon filament between separate upper and lower sheets using adhesive. See col. 4 lines 23-32. Isaacs et al does not recite detaching / heating the second material.

As to claim 1, it would have been obvious to one of ordinary skill in the art to cut a nylon monofilament to the length specified by Isaacs since McGill et al, also directed to Lower Extremity Amputation Protection, teaches cutting a nylon filament to obtain a desired length for Lower Extremity Amputation Protection.

As to "automated process" and "heating the second material", it would have been obvious to one of ordinary skill in the art to make Isaacs et al's medical test device having 90 degrees oriented nylon filaments bonded between two sheets by adhesively coating *continuous upper and lower sheets* with thermosensitive adhesive and heating / bonding spaced 90 degree oriented nylon filaments between the sheets since:
(1) Schwobel et al suggests automating a process for making a medical test device so as to obtain low production cost and high production rate - the automated process including laminating continuous material together in a continuous process and cutting the continuous laminate to obtain individual medical test devices and (2) it is well known / conventional in the bonding art to heat / bond individual 90 degree oriented members between continuous sheets coated with thermosensitive adhesive as exemplified by Mohr and Orzelek et al.

As to claims 5-13, the claimed dimensions of the second material (corresponding to the filament) and the first material (corresponding to the sheet) would have been

obvious in view of Isaacs teachings regarding the dimensions and materials for the filament and sheet and the use of the medical test implement for the care and treatment of diabetes. As to claim 10, a plastic sheet being taken as well known / conventional per se); it being noted that the suggestion to use a sheet is found in Isaacs..

9) **Claims 2-4 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaacs et al in view of McGill et al, Schwobel et al, Mohr and Orzelek et al as applied above and further in view of Footscreening ("Foot Screening-Care of the Foot in Diabetes") and optionally Lindley (US3511735).**

As to claims 2-4, it would have been obvious to heat the nylon filament to eliminate curvature since (1) Footscreening teaches that the nylon filament must be straight and (2) it is known in the filament art to improve the uniformity of a filament by heating the filament to eliminate curvature and make the filament straight as evidenced for example by Weihrauch.

As to claim 14, the limitation therein would have been obvious in view of Footscreening's suggestion to inspect for bent filaments and the testing of filaments suggested by McGill et al.

As to claims 15-18, it would have been obvious to "automate" the folded embodiment of Isaacs and use heat activated adhesive in view of (a) the above noted suggestion from Schwobel et al to automate a process for making a medical test implement using continuous sheet material, (b) the above noted suggestion from Mohr and Orzelek to bond 90 degree oriented members to a continuous sheet using heat activated adhesive and optionally (c) Lindley's disclosure to bond handles to a

continuous folded sheet by inserting the handles in the fold. The limitation of perforating the sheet would have been obvious since (a) Isaacs et al and Footscreening teach folding a sheet and Footscreening additionally suggests perforating at the fold in order to facilitate folding.

Remarks

10) The remaining references are of interest.

11) No claim is allowed.

12) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D. Maki whose telephone number is 703-308-2068. The examiner can normally be reached on Mon. - Fri. 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball can be reached on (703) 308-2058. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Steven D. Maki
September 30, 2003

STEVEN D. MAKI
PRIMARY EXAMINER
~~GROUP 1300~~
AU 1733

9-30-03